

Notice of Allowability

Application No.

10/731,074

Examiner

Michael P. Barker

Applicant(s)

ELOKDAH ET AL.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 09/06/05.
2. ☒ The allowed claim(s) is/are 1-9.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 03/08/04; 06/23/04; 09/08/05
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 1.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

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DETAILED ACTION

Claims 1-9 are currently pending in the instant application. Restriction was required by the Examiner. Applicant elected Group I (**Claims 1-6 and 8**) and further selected a species. Applicant has chosen to cancel **Claims 11-12** and **Claims 14-21**, include **Claims 9-10** in **Claim 7**, and renumber **Claim 13** as **Claim 9**, via an Examiner's Amendment, as explained below.

Priority

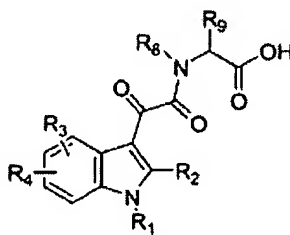
This application claims benefit of U.S. Provisional Application No. 60/432,331 filed December 10, 2002.

Information Disclosure Statement

Applicant's information disclosure statements (IDS), filed on (1) March 8, 2004, (2) June 23, 2004, and (3) September 8, 2005, have been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Response to Restriction

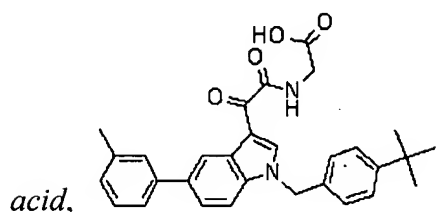
Applicant's election with traverse of Group I, **Claims 1-6 and 8** (in part), drawn to



compounds represented by Formula (I), , and specific compound of

Claim 1, {[1-(4-tert-butylbenzyl)-5-(3-methylphenyl)-1H-indol-3-yl](oxo)acetyl]amino}acetic

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, found in Example 1 on p. 19 of the *Specification* is acknowledged. Upon further examination, **Claims 1-9**, are drawn to allowable subject matter.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicant, an amendment may be filed as provided by C.F.R. § 1.312. To ensure consideration of such an amendment, it must be submitted no later than the payment of the issue fee.

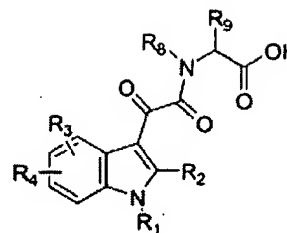
Authorization for this examiner's amendment was given in a telephone interview with Leslie Aberman on October 24, 2005. This application has been amended as follows:

1. Amend Claim 1 as follows: *Page 27 of the Claims, line 27*, delete "C1-C6 hydroxyalkyl," ; *Page 28 of the Claims, line 1*, delete "HSCH₂-".
2. Amend Claim 7 as follows: *Page 30 of the Claims, line 1*, after the words "in a mammal", add ", for treatment of thrombosis or fibrinolytic impairment in a mammal, wherein the thrombosis or fibrinolytic impairment is associated with formation of atherosclerotic plaques, venous and arterial thrombosis, myocardial ischemia, atrial fibrillation, deep vein thrombosis, coagulation syndromes, pulmonary fibrosis, cerebral thrombosis, thromboembolic complications of surgery or peripheral arterial occlusion," (Note: the remainder of Claim 7 is unchanged).
3. Amend Claim 13 as follows: *Page 31 of the Claims, line 32*, delete "A" and add "The" ; *Page 31 of the Claims, line 32*, after the word "method", add "of Claim 7".

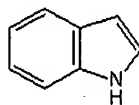
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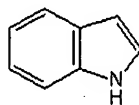
4. Cancel Claims 9-12 and 14-21, *pp. 31-33 of the Claims.*

Reasons for Allowance



The present invention relates to compounds of Formula (I), depicted in **Claim 1**, as well as various methods of use of these compounds.



Derivatives of indole, , are known in the art for their uses in treating a variety of ailments, including heart disease; *see*, for example, U.S. Patent No. 6,232,327 (Nickel, et al.), issued May 15, 2001 and U.S. Patent No. 4,851,406 (Mertens, et al.), issued July 25, 1989. While both of the aforementioned patents disclose a variety of indole derivatives, neither discloses, suggests, teaches, nor anticipates Applicant's invention.

The novel and nonobvious feature of the whole subject matter claimed appears to reside in the nature of Applicant's substitutions and combination of substitutions.

The closest prior art is Nickel et al., U.S. Patent No. 6,232,327, issued May 15, 2001. Nickel also teaches indole derivatives, though none anticipate nor disclose Applicant's claimed invention. Thus, while the aforementioned compounds taught by Nickel are similar in structure to those compounds of the instant application, none of the documents known so far (including those referred to in Applicant's 1449) show the precise substitutions made by Applicant.

Applicant's invention relates to compounds of Formula I as well as methods of using compounds of Formula I in the treatment of various diseases related to the inhibition of

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plasminogen activator inhibitor-1 in mammals. Support for Applicant's methods claims can be found in the references listed on the accompanying Notice of References Cited (PTO-892).

Nickel's claimed invention neither teaches nor suggests Applicant's instantly claimed invention, nor does it provide motivation to one of ordinary skill in the art to synthesize Applicant's compounds of Formula I. Moreover, Applicant's methods claims find ample support in the literature. Therefore, the whole subject matter, as claimed, is both novel and nonobvious.

References Cited

If a copy of a provisional application listed on the bottom portion of the accompanying Notice of References Cited (PTO-892) form is not included with this Office action and the PTO-892 has been annotated to indicate the copy was not readily available, the copy could not be readily obtained when the Office action was mailed. Should Applicant desire a copy of such a provisional application, Applicant should promptly request the copy from the Office of Public Records (OPR) in accordance with 37 CFR 1.14(a)(1)(iv), paying the required fee under 37 CFR 1.19(b)(1). If a copy is ordered from OPR, the shortened statutory period for reply to this Office action will not be reset under MPEP § 710.06 unless Applicant can demonstrate a substantial delay by the Office in fulfilling the order for the copy of the provisional application. Where the applicant has been notified on the PTO-892 that a copy of the provisional application is not readily available, the provision of MPEP § 707.05(a) that a copy of the cited reference will be automatically furnished without charge does not apply. Copies of references provided by Applicant will not be furnished to Applicant.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Barker whose telephone number is (571) 272-4341. The examiner can normally be reached on Monday-Friday 8:00 AM- 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699. The unofficial fax phone for this group are (571) 273-8300.

When filing a FAX in Technology Center 1600, please indicate the Header (upper right) "Official" for papers that are to be entered into the file, and " Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is viable through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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